K02 4159

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stryker
ENDOSCOPY

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name:	System, Image Processing
Common and Usual Name:	Strykerware™ Office Portal/Media Archive
Proprietary Name:	Strykerware™ System

This 510(k) summary and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The Strykerware™ PACS System is substantially equivalent in safety and efficacy as the currently marketed RemoteImage™ System and AMICAS Web/Intranet Image Server which were cleared under 510K#'s K994228 and K970064 respectively.

The Stryker Strykerware™ PACS System is a medical system that is designed to allow access to medical images and related data for physicians and other licensed professionals. The system receives images and medical data from image acquisition devices or other PACS (Picture Archive and Communication System) networks. The system's software includes an integrated web-based viewing and storage archival applications. The Strykerware™ System allows for the transfer of medical images and data between locations such as but not limited to a physicians operating suite.

The intent of the Strykerware™ System is to allow an office-based practice to convert from a paper to paperless environment and to create a flow of medical images and information between the office and the operating suites of the physicians belonging to that practice.

The Strykerware™ System conforms to the following voluntary standards: ACR/NEMA DICOM, ANSI/AAMI SW68 - "Medical device software – Software life cycle processes", and IEC 60601 – "Medical Electrical Equipment."

The technological differences between the Stryker Strykerware™ System and the predicate RemoteImage™ and AMICAS devices do not raise new issues of safety and efficacy of the predicate devices. Therefore, the Stryker Strykerware™ System is substantially equivalent to the currently marketed RemoteImage™ and AMICAS Web/Intranet Image Server.

Jerry Dickerson
Senior Project Engineer
Stryker Endoscopy

Date: 12-13-02

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 0 2003

Mr. Evan Norton
Product Manager
Stryker Endoscopy
5900 Optical Court
SAN JOSE CA 95138

Re: K024159
Trade/Device Name: Strykerware PACS System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: December 13, 2002
Received: December 17, 2002

Dear Mr. Norton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

December 12, 2002

510(k) Number (if known): K02 4159

Device Name

Indications for Use:

The Strykerware™ PACS System is a system designed to provide licensed medical professionals access to medical images. This product is intended to be used for reviewing and storing images from a variety of modalities. Strykerware™ is the system with software installed on a computer configured with connections to image acquisition devices, image storage locations and the internet. The system facilitates the transferal of images between local and remote locations (including but not limited to a licensed medical professional's operating suite). The users of Strykerware™ are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, and urologists.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024159